UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

K. SEAN O'NEIL, *et al.*, Plaintiffs, v. ST. JUDE MEDICAL, INC., *et al.*, Defendants.	No. C13-0661RSL ORDER DENYING DEFENDANTS' MOTION TO DISMISS

This matter comes before the Court on "Defendants' Amended Motion to Dismiss." Dkt. # 10. Plaintiff K. Sean O'Neil alleges that defendants failed to manufacturer its implantable cardiac defibrillator ("ICD") device in a manner that was consistent with the manufacturing and process changes approved by the Food and Drug Administration ("FDA") between 2005-2010. Complaint (Dkt. # 1) at ¶ 51. In particular, plaintiff alleges that the Riata leads on his ICD were subject to premature abrasion and protrusion through the insulation because defendants failed to (a) manufacture uniform insulation diameters, (b) consistently apply lubricious interface between insulation, (c) comply with the approved methods and specifications for curing and sterilization of the leads, and (d) properly crimp the leads, all as required by FDA regulations and the FDA-approved design criteria. Id. at ¶¶ 52-57. Plaintiff alleges facts from which one could reasonably infer that defendants were aware of the defects in the insulation of the Riata leads but failed to take timely and adequate measures to analyze problems and alert the FDA, medical providers, and/or customers. Id. at ¶¶ 46-50, 59-64, and

76. The FDA ultimately recalled the Riata leads because the abrasion of the insulation could lead to externalization of the leads. Id. at ¶ 67. Plaintiff further alleges that externalization of the leads exposes them to materials and fluids that cause them to malfunction, sending unnecessary and painful shocks of electricity to the heart or preventing the ICD from working altogether. Id. at ¶¶ 53-54. Finally, plaintiff alleges that he suffered electrical shocks from his ICD, he had to have it surgically removed and replaced in October 2012, and his surgeon confirmed that his Riata lead was defective. Id. at ¶ 1 and ¶ 6. Based on these allegations, plaintiffs have asserted three strict liability claims under the Washington Products Liability Act, RCW 7.72 *et seq*., namely manufacturing defect resulting from the failure to comply with the specifications approved by the FDA (Count 1), failure to comply with a list of federal standards that were incorporated into the Conditions of Approval for the ICD (Count 2), and breach of the on-going duty to evaluate the risks posed by the product and provide necessary warnings (Count 3). Plaintiffs allege that the product defect engendered by the failures set forth in the complaint caused physical injuries, emotional and mental distress, economic loss, and other damages. Defendants seek dismissal of all of plaintiffs' claims on the ground that the were not adequately alleged under Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007). Defendants also seek dismissal of Count 2 on the ground that it is preempted by the Medical Devices Amendments of 1976.

Having reviewed the Class Action Complaint and the memoranda submitted by the parties,[1] the Court finds as follows:

A. Adequacy of the Pleadings

Pursuant to Fed. R. Civ. P. 8(a)(2), a complaint must include "a short and plain statement of the claim showing that the pleader is entitled to relief." Where defendant

[1] Plaintiffs allege that defendant obtained the FDA's pre-market approval for the original Riata lead application. Complaint (Dkt. # 1) at ¶ 24. The Court need not take judicial notice of that or any other matter outside the pleading in order to determine the adequacy of the existing allegations.

This matter can be decided on the papers submitted. Defendants' request for oral argument is, therefore, DENIED.

challenges the adequacy of a complaint under Fed. R. Civ. P. 12(b)(6), the Court assumes the truth of the plaintiffs' allegations and draws all reasonable inferences in the plaintiffs' favor. Usher v. City of Los Angeles, 828 F.2d 556, 561 (9th Cir. 1987). In order to survive a motion to dismiss, plaintiffs' allegations must give rise to something more than mere speculation that plaintiffs have a right to relief. Twombly, 550 U.S. at 555. The complaint must offer "more than labels and conclusions" or a "formulaic recitation of the elements of a cause of action." Id. Detailed factual allegations are not required, however: the question for the Court is whether the facts set forth in the complaint state a "plausible" ground for relief. Id. at 570.

Plaintiffs have provided a short and plain statement of the facts giving rise to a plausible claim for relief under each cause of action asserted in the complaint. They have alleged the standards that governed defendants' conduct, specific breaches of those standards, and resulting damages. Defendants utilize a number of techniques to overcome the allegations of the complaint, but none is availing in the context of a motion to dismiss. Defendants may not, for example, simply ignore the facts alleged in the complaint. See Motion (Dkt. # 10) at 9 (asserting that plaintiffs "do not allege any facts that plausibly suggest that the FDA ever imposed" requirements regarding insulation diameters when in fact plaintiffs alleged at ¶ 52 that "insulation diameters are required by the design specifications, PMA, and/or federal requirements to be consistent"). Nor may defendants refuse to draw perfectly reasonable inferences in plaintiffs' favor in order to argue that a claim fails as a matter of law. See Motion (Dkt. # 10) at 10 (asserting that there are no factual allegations that plausibly suggest that plaintiff was injured as a result of the defect despite the fact that the type of harm plaintiff suffered was exactly the type of harm one would expect from the externalization of the lead and his surgeon confirmed the existence of a defect).

Defendants do not argue that plaintiffs' complaint contains nothing more than a formulaic recitation of the elements of the claim, but rather suggest that the complaint is defective because the factual allegations are not supported by additional, underlying factual

allegations. Layers of detailed factual allegations are not required by Fed. R. Civ. P. 8(a) or Twombly, however. In order to allege causation, for example, plaintiffs need not definitively allege what his surgeon would have done had defendants accurately evaluated the risks associated with the Riata leads and timely notified the FDA. While plaintiffs will ultimately have to prove that if defendants had properly reported the adverse events, Mr. O'Neil could have avoided the discomfort of unnecessary electrical shocks and the uncertainty of having his defibrillator turned off until he was awaiting surgery, that is not their burden at this point in the litigation. For purposes of the causes of action alleged, the allegations regarding the manufacturing and reporting standards imposed by federal regulation and the approval process, the specific manufacturing defects arising from noncompliance with those standards, the FDA investigation and recall, defendants' knowledge of product defects and subsequent reporting failures, the impact the alleged defects would have on the functioning of an ICD, the nature of plaintiff's injuries, and the condition of his Riata lead upon removal, considered together, are sufficient to state plausible claims for relief.[2]

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[2] The Court acknowledges that a number of products liability claims related to the Riata leads have been dismissed for failure to satisfy Twombly. In each of those cases, however, the factual allegations were more conclusory than those present here and failed to raise a plausible inference that defendant could be liable. See Scianneaux v. St. Jude Med. S.C., Inc., 2013 WL 4417455, at * 4 (E.D. La. Aug. 19, 2013) (plaintiff alleged only that defendant "deviated from FDA requirements" and the product specifications without identifying the requirements that were violated or explaining how the design or manufacture of the product deviated from those requirements); Knoppel v. St. Jude Med., Inc., 2013 WL 3803612, at *2 (C.D. Cal. May 7, 2013) (allegation that product defect increased risk of injury to patients did not give rise to a plausible inference that the Riata lead in plaintiff's ICD was defective or that plaintiff's unspecified injury was causally-related to the alleged defect); Viserta v. St. Jude Med., Inc., 2012 WL 667814, at *4 (D.S.C. Feb. 29, 2012) (plaintiff failed to allege facts from which one could plausibly infer a causal connection between the alleged manufacturing defect and her injury).

At page 14 of their opening memorandum, defendants challenged the legal viability of plaintiff's claim that they had violated two of the specified regulations (rather than simply challenging the adequacy of the factual allegations). In particular, defendants argued that they could not, as a matter of law, violate 21 C.F.R. § 814.3 and § 814.9 because it is logically and legally impossible for defendants to have violated the definitions section of the regulations or duties imposed on the FDA. These arguments appear to have merit, but instead of seeking dismissal of the relevant portion of Count 2, defendants sought dismissal of all of Count 2 without addressing the many other regulations that appear

B. Preemption

Defendants argue that Count 2, which is based on an alleged failure to comply with federal regulations regarding the manufacture, marketing, and sale of the Riata leads, is preempted by the Medical Device Amendment of 1976 ("MDA"). The Ninth Circuit recently addressed MDA preemption in Stengel v. Medtronic Inc., 704 F.3d 1224 (2013). Faced with three hard-to-reconcile Supreme Court decisions,[3] the Ninth Circuit concluded that a state failure-to-warn claim based on a manufacturer's failure to report adverse events to the FDA as required by federal law was not predicated wholly on federal law (and therefore impliedly preempted by 21 U.S.C. § 337(a)) and would not impose a state requirement that was "different from, or in addition to" the federal requirements (and therefore expressly preempted by 21 U.S.C. § 360k). The court noted that Arizona tort law includes a cause of action for failure-to-warn, and that such claims may be predicated on an alleged failure to notify a third party, such as the FDA, if the information would likely reach those whose safety depends on the warning. Stengel, 704 F.3d at 1233.[4] Because the Stengels' claim paralleled and did not add to a federal requirement under the MDA, the failure-to-warn claim could proceed. The fact that the underlying obligation to report adverse events to the FDA arose solely out of the Food, Drug, and Cosmetic Act was not fatal to the Stengels' claim.

The same result applies here. States have traditionally exercised their police powers to protect the health and safety of their citizens, and Congress has not "clearly signaled

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to be directly applicable.

[3] The three cases are Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001), and Riegel v. Medtronic, Inc., 552 U.S. 312 (2008).

[4] The concurrence pointed out that, because the Stengels had to plead between the Scylla of § 337(a) preemption and the Charybdis of § 360k preemption, they "face[d] a causation hurdle that would not otherwise exist. To prevail, they will ultimately have to prove that if Medtronic had properly reported the adverse events to the FDA as required under federal law, that information would have reached Mr. Stengel's doctors in time to prevent his injuries. . . . But at this juncture . . . the Stengels' allegations of causation are adequate." Stengel, 704 F.3d at 1234-35 (Watford, J., concurring).

its intent to deprive States of any role in protecting consumers from the dangers inherent in many medical devices." Stengel, 704 F.3d at 1231 (quoting Lohr, 518 U.S. at 486-87). Plaintiffs allege that defendants breached their duty of care under the Washington Product Liability Act and that the scope and nature of the duty owed is established by the listed federal regulations (which were also incorporated into the Conditions of Approval for the product). Under Washington tort law, a claim may, in appropriate circumstances, be based on a duty of care established by an applicable statute or regulation. See Barrett v. Lucky Seven Saloon, Inc., 152 Wn.2d 259, 269 (2004) (applying Restatement (Second) of Torts § 286 (1965) when determining whether a legislative enactment or administrative regulation provides the standard of conduct of a reasonable man); Schooley v. Pinch's Deli Market, Inc., 134 Wn.2d 468, 474-75 (1998) (same).[5] As was the case in Stengel, plaintiffs' second cause of action specifically alleges a violation of Washington law based on a failure to comply with federal regulations. Such a claim parallels the underlying federal requirements and imposes no different or additional state requirements: defendants' preemption argument therefore fails.

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[5] Restatement (Second) of Trots § 286 (1965) provides:

> The court may adopt as the standard of conduct of a reasonable man the requirements of a legislative enactment or an administrative regulation whose purpose is found to be exclusively or in part
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> (a) to protect a class of persons which includes the one whose interest is invaded, and
> (b) to protect the particular interest which is invaded, and
> (c) to protect that interest against the kind of harm which has resulted, and
> (d) to protect that interest against the particular hazard for which the harm results.

It is at least arguable that many, if not all, of the regulatory requirements on which Count 2 is based were intended to protect the health and well-being of plaintiff and other consumers of medical devices against the type of hazards and harms plaintiff actually experienced.

For all of the foregoing reasons, defendants' motion to dismiss (Dkt. # 10) is DENIED.

DATED this 22nd day of November, 2013.

Robert S. Lasnik
United States District Judge